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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,625	12/06/2005	Jurgen Herber Vollhardt	4804-2	2804

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
07/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,625	VOLLHARDT ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 16* is/are pending in the application.

4a) Of the above claim(s) *1 - 9, 12, 15, 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,11,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group III with a compound of phytanic acid and a condition being treated or prevented of cellulite in the replies filed on March 19, 2008 and May 27, 2008 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Comments and Notes

Claims 10, 11, 13 and 14 of the instant application are use claims. For the purposes of applying art below, these claims are being interpreted as a method of using a compound of formula I for the treatment or prevention of cellulite, the elected condition.

Claim 1 is only being examined to the extent that it defines a compound of formula (I), a limitation present in the claims currently under examination.

Claim Objections

2. Claim 10 is objected to because of the following informalities: it appears that a typographical error is present in line 12 in "lipid und energy metabolisms". Appropriate correction is required.

Claim Rejections - 35 USC § 112 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11, 11, 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In describing compound (I), one possible value for R^1, R^2 and R^3 is "a residue derived from an amino acid or peptide". None of the residues derived from an amino acid or peptide meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus of residues derived from an amino acid or peptide encompassed by the claim, since there is no description of the structural relationship of these derivatives provided in the specification and Applicant has not provided a description as to how the base amino acid or peptide may be changed while still remaining a derivative.

5. Claims 10, 11, 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of cellulite and subcutaneous fat pads, does not reasonably provide enablement for the prevention of any of the conditions listed in claims 10 and 13 or the treatment of conditions other than cellulite and subcutaneous fat pads. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The disclosure and claims of the application have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) as to undue experimentation

The factors include:

1. The nature of the invention;
2. The breadth of the claims;
3. The predictability or unpredictability of the art;
4. The amount of direction or guidance presented;
5. The presence or absence of working examples
6. The quantity of experimentation necessary;
7. The state of the prior art; and
8. The relative skill of those skilled in the art.

Each relevant factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

1. The nature of the invention, the breadth of the claims: A compound as defined by formula (I) of claim 1 is provided in a topically administered composition for the prevention or treatment of a variety of conditions. Examples of conditions claimed include cellulite, subcutaneous fat pads, greasy hair, dandruff formation, conditions caused by a damaged or injured skin barrier, eczema and vitiligo.

2. The amount of direction or guidance presented, the presence or absence of working examples: Results from a trial of patients suffering from cellulite using a composition according to the present invention is presented on p 25 of the instant specification.

3. The quantity of experimentation necessary, the state of the prior art, and the relative skill of those skilled in the art: The relative skill of those skilled in the art is high. A wide variety of conditions are presented in the claims and both the prevention and treatment of these conditions is claimed. While the art has shown that compositions comporising compounds of formula (I) (see, for example, deLong et al. US 2004/0131648) are useful for the treatment of cellulite, the Examiner was unable to find evidence that such compositions could treat infections resulting from a cut to the skin,

for treating greasy hair, strengthening the barrier function of the skin or that the application of compounds of formula (I) resulted in alteration in intracellular DNA synthesis, DNA repair mechanisms or post-translational modification of constituents of connective tissue or the other conditions claimed by Applicant. deLong et al. discloses that such compositions are useful for beautification of the skin, including treating textural abnormalities, lines, wrinkles, sagging, and some conditions such as psoriasis (paragraphs [0017] and [0019]).

"To prevent" (dictionary.com entry, accessed 11/28/07) is defined as to keep from happening or arising, make impossible (p 3). Neither Applicant nor the prior art presents evidence or recognizes that these compositions can make impossible the formation of cellulite, greasy hair, etc.

Since the term "treating" is inclusive of various administration schemes and thus provides adequate coverage for all reasonably successful therapies (prophylactic or active), the examiner recommends deleting the term "preventing" and simply reciting "treating" only instead.

Claim Rejections - 35 USC § 112 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 10, 11, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. These claims provides for the use of a compound of formula (I) as defined in claim 1 for the production of a medicament or cosmetic preparation to be administered topically, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

8. Claims 10, 11, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "in particular" in claim 1, line 5 and claim 10, line 8 renders the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

9. Claims 10, 11, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are dependent from a withdrawn claim, claim 1.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

11. Claims 11, 11, 13 and 14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 10, 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over deLong et al. (US 2004/0131648).

deLong et al. discloses compounds such as fatty acid analogs that function as receptor ligands to encourage skin differentiation and discourage excess skin proliferation (abstract). The compounds can be used in compositions to provide enhanced and permanent beautification of the skin (paragraph [0009]). Beautification of the skin includes the reduction of texture abnormalities of the skin (paragraph [0017]). Among the fatty acids analogs suitable for use in the composition is phytanic acid (paragraph [0043]). These compositions disclosed by deLong et al. can be topically administered (paragraph [0178]).

deLong et al. does not explicitly topically apply a composition comprising phytanic acid to treat cellulite.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition comprising phytanic acid and use the composition to treat a textural abnormality of the skin, as these elements are all taught by deLong et al. Cellulite, which is also referred to by the names “orange skin”, "orange peel skin" or "cottage cheese skin", is a condition that manifests itself by altering the texture of the skin and therefore, the method of beautifying the skin taught by deLong et al. using a topical composition comprising phytanic acid is a method of treating cellulite.

16. Claims 10, 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ailhuad et al (US 5,728,739) in view of Menon et al. (WO 01/66080) and Halvorsen et al. (US 2001/0041708).

Ailhaud et al. discloses a composition comprising a compound which displays affinity for the nuclear receptors of retinoic acid (namely, RAR and RXR) and a fatty acid (col 3, ln 38 – 43). A variety of retinoids (col 5, ln 4 – col 6, ln 36) and fatty acids (col 6, ln 37 – col 7, ln 10) are disclosed as suitable for use in the composition. These compositions are suited for the curative and/or prophylactic treatment of patients afflicted with insulin resistance or by all other physiopathologies associated with this disease state (col 4, ln 54 – 59). An excessive imbalance between lipid synthesis and lipolysis can manifest itself gradually by the appearance of thick skin with a surface which is often irregular (“orange peel”) and of more or less flabby or gelatinous

consistency (col 2, ln 26 – 40). Further progression can cause localized overweight to definite stoutness to true obesity (col 2, ln 40 – 43).

Ailhaud does not identify phytanic acid as a compound with affinity for a nuclear retinoic acid receptor or the topical application of the composition to treat "orange peel" skin.

Menon et al. discloses that phytanic acid, when topically applied, is globally activates retinoic acid receptors (RARs), retinoid X receptors (RXRs) and peroxisome proliferation activated receptor (PPAR) responsive genes (p 4, ln 1 – 6).

Halvorsen et al. discloses a method of combating cellulite or reducing localized fatty excess by administration of a composition comprising 10-trans-12-cis conjugated linoleic acid (paragraph [0002]). Cellulite is also referred to as "orange peel skin", "mattress phenomena" or the "cottage cheese effect" (paragraph [0003]). The compositions may be topically applied to treat these conditions (paragraph [0010]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition of a compound that bind to a nuclear retinoic acid receptor and at least one fatty acid, taught by Ailhaud et al. as a composition suitable for treating a condition that can lead to "orange peel skin" and to use phytanic acid as the RAR/RXR binding compound, as taught by Menon et al. As demonstrated by Halvorsen et al., compositions such as those taught by Ailhaud et al. can be administered topically and provide beneficial results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW